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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/468,647	12/21/99	GORDON	R B0192/7011

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EXAMINER
ANDRES, J

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/468,647

Applicant(s)

GORDON ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 5,8-10,13,16-20,22-29,32-38,48-53 and 57-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7,11,12,14,15,21,30,31,39-44,54-56 and 72 is/are rejected.
- 7) ☒ Claim(s) 1-4,6,7,11,12,14,15,21,30,31,39-44,54-56 and 72 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 11 is acknowledged. Claims 45-47 were inadvertently omitted from this group and are rejoined. The restriction requirement is made final. Claims 1-72 are pending in this application. Claims 5, 8-10, 13, 16-20, 22-29, 32-38, 48-53, and 57-71 are withdrawn from consideration as being drawn to a non-elected invention.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on 22 December 1998. It is noted, however, that applicant has not filed a certified copy of the British application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

3. Applicant's information disclosure statement submitted 2 October 2000 in paper no. 6 has been considered in full. The information disclosure statement submitted 9 February 2001 in paper no. 7 has not been considered because the references have not been provided.

Specification

4. The disclosure is objected to because of the following informalities: The sequences in the figures are not referred to by the identification number of an entered sequence. Also, there is a blank space on p. 21 where an accession number has not been filled in.

Appropriate correction is required.

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Claim Objections

5. Claims 1-4, 6, 7, 11, 12, 14, 15, 21, 30, 31, 39-44, 54-56, and 72 are objected to because of the following informalities: Sequences must be referred to by the identification number of an entered sequence, not by reference to a figure. Claim 21 is objected to because it depends off a non-elected claim. Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The intended use of the invention does not alter the invention itself.

Appropriate correction is required.

Claim 42 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 40. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-4, 6, 7, 14, 30, 39-43, 54-56, and 72 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims do not require that the nucleic acid be isolated and thus read on a product of nature.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4, 6, 7, 11, 12, 14, 15, 21, 30, 31, 39-47, 54-56, and 72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide comprising SEQ ID NO: 3, does not reasonably provide enablement for equivalents, isoforms, variants, or derivatives of the polynucleotide, for sequences identified by hybridization, or for sequences comprising functional domains. Applicant has described a polynucleotide encoding VEGF-X. However, Applicant has not described the characteristics of this nucleic acid sequence so that one of skill in the art could predictably identify other sequences encoding VEGF-X molecules. Applicant has not described the properties or characteristics of the sequences that are required to encode a functional protein that is identifiable as VEGF-X. Thus, the essential characteristics of nucleic acids encoding variants of VEGF-X proteins are not described. Claims 39-47 and 54-56 are drawn to sequences comprising CUB domains or VEGF-like domains of the disclosed sequence. Applicant has provided evidence that the CUB domain inhibits proliferation of HUVECs. However, Applicant has not provided guidance by which one of skill in the art could predictably determine what sequences comprising this sequence would be inhibitory. The molecule from which the domain is derived is stimulatory and the claims include sequences comprising other VEGF domains and the CUB region, as well as sequences in which the additional regions are unspecified; one of skill would not be able to predict, based on the instant

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specification, whether these molecules would be inhibitors or agonists, or would function at all. Thus one of skill in the art would require additional guidance in order to be able to predict what sequences comprising this region would have the same characteristics. In contrast, Applicant teaches that the VEGF domain is not functional, possible due to incorrect folding. Thus one of skill in the art would not predictably be able to use this sequence, or sequences comprising it. Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids that might potentially encode such proteins where the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result in the particular characteristics of VEGF-X, and what sequences would conserve CUB function or allow VEGF-like function, in order to practice the invention commensurate with the scope of the claims without undue experimentation.

10. Claims 1-4, 6, 7, 11, 12, 14, 15, 21, 30, 31, 39-47, 54-56, and 72 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a genus, i.e polynucleotides encoding variants, equivalents, isoforms, and derivatives of VEGF-X. Applicant has disclosed one species, the polynucleotide of SEQ ID NO: 3, but has not disclosed sufficient species for the broad genus of any polynucleotide encoding VEGF-X. Applicant has further not described the essential features of sequences comprising only regions of the disclosed sequence.

The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is insufficient information regarding the relation of structure to function: Applicant states that the VEGF region is not functional, and that the CUB domain functions as an antagonist. The VEGF region therefore does not define the essential features of the genus of VEGF-X molecules, or of sequences comprising that region, as in claims 43, 45, and 47. Similarly, since at least one sequence comprising the CUB domain, that of the entire molecule, has an opposite function to the CUB domain, more information is required to define the essential features of sequences comprising this domain, as claimed in claims 39-42, 44, 46, and 54-56. Further, structural features that could distinguish the compounds in the genus described as VEGF-X from other VEGF-like compounds are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed: there is no guidance in the art as to what the defining

characteristics of VEGF-X might be. Thus, no identifying characteristics or properties of the instant polynucleotides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, the disclosure of SEQ ID NO:3 is insufficient to describe the genus. Further, the essential features of sequences comprising CUB domains or comprising VEGF domains are not set forth, since the VEGF domain is not functional and sequences comprising the CUB domain can clearly have entirely different properties than the CUB domain itself. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-4, 6, 7, 11, 12, 14, 15, 21, 30, 31, 39-47, 54-56, and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite in the reference to the claimed molecules by reference to a figure, rather than to the identification number of an entered sequence.

The claims are further indefinite in the recitation of "functional equivalent", "derivative", "variant" and "bioprecursor". These terms are not defined in the specification; one of skill in the art would not be able to determine what molecules were within the scope of the claims. The claims are further indefinite in the recitation of molecules identified by hybridization. The

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definitions in the specification are not limiting: only examples are provided. Thus the skilled artisan would not be able to determine what molecules were intended to be encompassed.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
October 1, 2001


YVONNE EYLER, PH.D.
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